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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,585	05/24/2001	Stanley R. Mandel	032781-003	2107

7590

09/11/2002

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EXAMINER

VANATTA, AMY B

ART UNIT	PAPER NUMBER
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3765

DATE MAILED: 09/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/864,585

Applicant(s)

MANDEL ET AL.

Examiner

Amy B. Vanatta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 5-11, 16 and 19-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12-15, 17, 18 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species of the device: I. clip
II. clip applier

Species of the material: A. metal
B. polymer

Species of the antimicrobial or antibiotic composition:
i. coating
ii. incorporated into the material of the device

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, applicant must select of one I or II, one of A or B, and one of i or ii. Currently, no claims are generic to all species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Mary Grant on August 27, 2002 a provisional election was made with traverse to prosecute the invention of the clip (I), the polymer (B), and the coating (i), claims 1-4, 12-15, 17, 18, and 27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-11, 16, and 19-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

4. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Specifically, applicant provided two claims numbered as claim 26. Therefore, the second claim 26, which was misnumbered, has been renumbered as claim 27.

Claim Rejections - 35 USC § 102 and 35 USC § 103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 2, 12, 15 and 18 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kuehn et al (US 6,165,183).

Kuehn et al disclose a medical device which is made of a polymer (col. 12, line 16) and is coated with an antimicrobial coating (col. 12, lines 20-21). Kuehn teaches that the antimicrobial coating comprises "silver metal or silver compound", which includes silver ions as claimed. Kuehn also discloses the steps of coating as recited in claims 12, 15, and 18 (col. 12, lines 14-26). Kuehn discloses various medical devices which may be made of such coated material, including a clamping ring (600 or 630) as shown in Figs. 33-34 and a gripper (412) as shown in Fig. 18A. Such devices have a structure which forms a "clip" to the extent claimed. The recitation of the use of the clip for ligating or other purposes merely amounts to the intended use of the device, since the claim does not define any further structure which defines the claimed clip over the ring or gripper of Kuehn. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Alternatively, assuming *arguendo* that the claimed clip inherently has a structure which defines over the medical devices of Kuehn et al, one having routine skill in the art would recognize that the antimicrobial coated material disclosed by Kuehn would be

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advantageous in a ligating clip to the same extent that it is advantageous in the medical devices disclosed in the patent of Kuehn. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make a ligating clip out of the antimicrobial coated material of Kuehn et al in order to prevent or resist infection in the patient.

8. Claims 1-4, 12-15, 17, 18, and 27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fox, Jr. et al (US 5,019,096).

Fox et al disclose medical devices made of polymeric material (col. 3, lines 6-24) and having surfaces coated with an antimicrobial or antibiotic coating composition. Fox discloses a method for inhibiting growth of or killing microorganisms comprising coating the medical device with an antimicrobial or antibiotic coating composition as in claim 12. Fox teaches that the antimicrobial coating may comprise silver ions, and specifically discloses the use of various silver compounds as recited in claims 3 and 13 (col. 13, lines 36-45). Fox also discloses the use of quinolones, oxacillin, or cephalosporins in the antibiotic coating (col. 13, lines 47-51), as recited in claims 4 and 14. Fox discloses the use of a biodegradable polymer material, thus being absorbable as in claims 17 and 27. The coating disclosed by Fox functions to kill microorganisms in the manner recited in claim 18. Fox teaches that a device made of this coated material is a wound clip (col. 3, line 15). Such a clip meets the structure of the claimed clip. The recitation of the use of the clip for ligating, thus being a "ligating clip", merely amounts to the intended

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use of the device, since the claims do not define any further structure which defines the claimed clip over the clip disclosed by Fox. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).which is coated with th

Alternatively, assuming *arguendo* that the claimed "ligating clip" inherently has a structure which defines over the wound clip of Fox, it is noted that Fox teaches that medical devices which may be so coated are "those for use both externally and internally" and includes catheters, tubes, implants, wound clips, sutures, and grafts. Since ligating clips are a type of wound clip and fall into the grouping of medical devices which are for use internally, one having routine skill in the art would recognize that the coated material and method of Fox would be advantageous for use in the ligating clip in order to prevent or resist infection. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make a ligating clip out of the antimicrobial or antibiotic coated material of Fox in order to prevent or resist infection in the patient.

Conclusion

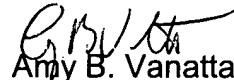
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy B. Vanatta whose telephone number is (703) 308-2939. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on (703) 305-1025. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3579 for regular communications and (703) 305-3579 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.


Amy B. Vanatta
Primary Examiner
Art Unit 3765

abv
August 28, 2002